

Notice of Allowability

Application No.

10/776,020

Applicant(s)

SHEHADA, RAMEZ EMILE
NECOLA

Examiner

Laura C. Hill

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
2. ☒ The allowed claim(s) is/are 1-4, 6-13, 15-19, 21-23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 1/23/07; 3/28/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Marc Brown on 20 April 2007.

In Claim 1, line 4

After "the tissue", please insert --within the surgical wound--

In Claim 7, line 4

After "the tissue", please insert --within the surgical wound--

In Claim 16, line 7

After "the tissue", please insert --within the surgical wound--

In Claim 21, line 6

After "the tissue", please insert --within the surgical wound--

Please **change the title to:**

Implanted Surgical Drain with Multiple Sensing Elements for Monitoring Internal Fluid Lumen.

Reasons for Allowance

Information Disclosure Statement

It is noted that the information disclosure statements filed 1-23-07 and 3-28-07 have been considered herein.

Terminal Disclaimer

The terminal disclaimer filed 6 March 2007 has been approved and overcomes a provisional obvious-type double patenting rejection with co-pending application 10/775,666 containing similar subject matter.

Claims 1-4, 6-13, 15-19, and 21-23 are allowed.

The following is an examiner's statement of reasons for allowance: the art of record alone or in combination fails to disclose or fairly suggest a surgical drain with drain holes configured to rest against the surface of the tissue and configured to not penetrate the tissue that has a sensing element affixed to the elongated drain conduit.

The following is the closest prior art:

Crowley (US 6,882,875) discloses an interventional device 30 insertable into the body and positioned against tissue 92 (column 5, lines 1-2, figure 5A) having elongated member 32 but *not having a drain lumen or drain holes* with sensing system 16 (column 3, lines 15-24, column 4, lines 13-29, figure 1) and fluorescence spectrum for detecting a normal tissue 82 and a cancerous tissue 80 but not for sensing a biochemical property (column 4, lines 55-65).

Fonger et al. (US 5,291,896) discloses a cardiac output probe assembly 10 with drainage tube 12 having output probe/sensor 14 affixed to and embedded within (figure 1), said tube is adapted for placement within (and thus *penetrating the tissue*) the thoracic cavity of a living body (column 3, lines 35-52, column 4, lines 29-32 and lines 50-56). There is no motivation to combine the device of Crowley with other surgical

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drains such as Fonger and (Russo US 4,317,452) since the known surgical drains penetrate inside the tissue and thus teach away from any combination.

Benaron et al. (US 5,769,791) discloses surgical tool 30,210 with tip 40 passing through or around internal body tissue (column 10, lines 29-38) or alternatively resting on tissue 207 and not penetrating through it (column 18, lines 14-15, figure 6) comprising first transmitting element 22, 241,242 provides a light control signal using optical fibers (column 9, lines 23-31, column 18, lines 15-18), first sensing element 24, 245, 246 that receives signals corresponding to the detected light (column 18, lines 20-21, figure 6). However, Benaron doesn't disclose a surgical drain having a tube with drain holes to transport drained fluid out of the body or sensor.

Mayevsky (US 5,916,171) discloses a device that simultaneously monitors NADH, CBF and other physiological properties using a bundle of optical fibers resting against the surface of the tissue (column 4, lines 10-20, column 6, lines 52-53, columns 9-10, table 3) but no surgical drain.

Frank (US 3,769,497) discloses a biomedical device having a surgical drainage tubing 13 coming from a catheterized patient having transmitting switch 19 and sensing device 16 for transmitting and detecting energy (column 2, lines 7-38, figure 1). One would not be motivated to modify the sensing devices of Benaron, Crowley or Mayevsky listed above with the drain since Frank discloses a drain that *penetrates* the tissue.

Takezawa et al. (US 5,108,364) discloses catheter 1 that is *implanted into a body cavity* and thus penetrates the tissue (column 3, lines 55-65) having temperature sensor 10 that detects energy and embedded within the catheter (column 4, lines 9-15), processor

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and display (column 4, lines 9-10) and drainage holes 5 (column 3, lines 29-38, figure 1A),.

Bedingham (US 5,421,328) discloses an arterial catheter 53 with oxygen sensor 69, carbon dioxide sensor 71, and pH sensor 73 affixed to a distal end of transmitting element/optical fibers 75,77,79 on an inner surface of the catheter (column 7, lines 46-51, column 8, lines 2-4 and figure 2). Thus the catheter is implanted into and penetrates a tissue.

Sullivan et al. (US 4,497,324) discloses a urinary, interperitoneal, intercardial, respiratory or intervacular catheter *penetrating* the tissue (column 5, lines 7-11) having drainage lumen 20 (column 3, lines 31-39), temperature transducer/sensor 32 imbedded in the catheter wall to detect temperature and convert said temperature to an electrical signal (column 3, lines 60-63), and a transmitting element/electrical lead 34 imbedded in the catheter wall (column 4, lines 19-20).

Yanda (US 4,413,633) discloses catheter tube 10 inserted into a urethra and thus penetrating the tissue that forms the urethra and connected to drainage tube 30 (column 2, lines 32-35 and lines 42-47), sensor 38 and transmitter on inner surface of the catheter (column 3, lines 18-39 and figure 2).

Pavoni et al. (US 5,906,584) discloses electrodes/sensors 5 on outer surface of catheter 3 but catheter is inserted within tissue, and a monitor/reading apparatus and a power supply/energy delivery transmitting element (column 4, line 36-column 5, line 8, figures 6-7). Also there is no drain with drainage holes disclosed.

Jenkins et al. (US 6,645,199) discloses apparatus 10 having push structure

18/elongated conduit *without drain and drainage holes* having loop structure 14 resting against a tissue region such as the pulmonary vein or *into* atria or not contacting a body tissue at all (column 5, lines 20-47, column 6, lines 11-54, column 16, lines 5-19, figure 1).

Frank (US 3,769,497) discloses a urine monitoring system with drainage conduit 12 coupled to a catheterized patient wherein the catheter *penetrates* the tissue and sensing device 16 not affixed to conduit (column 2, lines 6-19, figure 1).

Pavoni et al. (US 5,906,584) discloses an invasive body temperature measurement device rather than a surgical drain having needles 2 disposed within tissue with thermocouples/sensors 5 not associated with conduit 2 and reading apparatus (column 4, lines 40-67, figures 1-3).

Kaldany (US 5,334,171) discloses implantable tube 30 inserted into not resting against the surface of the vascular wall (column 3, lines 21-40) but no sensing element.

Alleyne (US 5,437,672) discloses shield 10 that rest against the outer surface area of the vertebral bone and having fenestrations 14 for draining fluid and blood naturally occurring (not formed from an artificially created surgical wound) (column 4, lines 45-60, column 5, lines 2-22) but no sensing element.

Sewell (US 5,141,503) discloses catheter 11 inserted into the wound site (but we do not know if it penetrates the tissue within the wound) having apertures 14 (column 3, lines 20-55) but no sensing element.

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Frazee (WO 92/11803) discloses cardiopulmonary monitoring system 100 that transmits and receives optical signals to and from the interior of the penetrated blood vessel via fiber optic catheter 10, monitor/display, and processing (see abstract, etc).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (hours vary).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C Hill
Examiner
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LCH



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SUPERVISORY PRIMARY EXAMINER

